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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,918	09/29/2006	Yoshinori Abe	4633-0189PUS1	5532

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EXAMINER	
GUGLIOTTA, NICOLE T	

ART UNIT	PAPER NUMBER
1783	

NOTIFICATION DATE	DELIVERY MODE
05/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,918	ABE ET AL.	
	Examiner	Art Unit	
	NICOLE T. GUGLIOTTA	1783	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2, 9 - 10, 12 - 15, 28 - 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 9 - 10, 12 - 15, 28 - 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 1, 2010 has been entered.

Examiner's Note

The Examiner acknowledges amendments to claims 2 & 29, as well as the cancellation of claims 4, 8 & 30. Claims 2, 9 - 10, 12 - 15 & 28 - 29 are currently pending.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Examiner acknowledges Applicant's submission of the English translation of their foreign priority document, JP 2004-100186.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 2, 9 - 10, 12 - 15, 28 & 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

First, claim 2 states, "...one end of the polymer chain is covalently bonded to the surface of the diamond-like carbon film, and polymer chain has a structure represented by any one of the following formulas..." Claim 29 contains a similar limitation. There is insufficient support for the attachment of the polymer chains claimed with the DLC via covalent bonds. Applicant's specification states the polymer chains described in claims 2 & 29 were attached by grafting (specification [0045] - [0049]). Claims 9 - 10, 12 - 15 & 28 are dependent on claim 2 and therefore also rejected.

Second, claim 28 is dependent upon claim 2 and specifically limits the biocompatible component to be a polymer of hydrophilic 2-hydroxypropyl methacryl amide. However, this compound is not a polymer chain with a structure of one of the three formulas stipulated in claim 2. A biocompatible component of a polymer of hydrophilic 2-hydroxypropyl methacryl amide is a different embodiment than the polymer chain structures described in claim 2. In addition, Applicant's specification discloses the hydrophilic 2-hydroxypropyl

methacryl amide compound was attached to the DLC surface by grafting, not covalent bonding. Thus, claim 28, as presently written, describes a single structure from a combination of different embodiments disclosed by the Applicant. The Examiner considers this to be new matter.

Third, claim 29 states, "...the polymer chain is covalently bonded via an ester linkage to the surface of the diamond-like carbon film..." There is insufficient support for an ester linkage in Applicant's specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 2, 12 – 15 & 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al. (U.S. Patent No. 7,033,602 B1), in view of New et al. (US 2004/0127475 A1), and further in view of Dang et al. (U.S. Patent No. 6,159,531).

In regard to claims 2 and 29, Pacetti et al. disclose a multilayered coating comprised of a primer, such as a diamond-like carbon (DLC) film (Col. 18, Lines 11 – 19) and a hydrogel, such as a polymer of vinyl monomers (Col. 3, Lines 32 – 35; Col. 18, Lines 20 - 21 & 28 - 32), which is applied to a medical device (base

material). Pacetti et al. are silent in regard to the specific types of vinyl monomers that may be used for the coating of their invention.

New et al. disclose biocompatible coatings for implantation devices comprised of polyvinyl esters (i.e. polyvinyl acetate), which has the chemical formula $-(CH_2\text{-}CHX)_n-$. Polyvinyl esters are biostable and minimize irritation to the vessel walls when the medical device is implanted (¶ [0061]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a vinyl polymer such as polyvinyl esters as the hydrogel in the invention of Pacetti et al. because News et al. teach polyvinyl esters are biostable and minimize irritation to vessel walls when the stent is implanted into the human body.

Both Pacetti et al. and New et al. are silent in regard to a covalent bond, specifically an ester linkage, bonding the vinyl polymers to the DLC surface.

Dang et al. teach using ester linkages (Col. 4, 25 – 31) for stable covalent bonds between biocompatible molecules and coatings applied to substrates (medical devices). Linkers, such as ester linkages, enhance exposure of the biocompatible molecules to the environment. Biocompatible molecules are more likely to maintain their natural conformation and bioactivity when given the space and freedom provided by the linkages (Col. 4, Lines 5 – 17).

Therefore, based upon the teachings of Dang et al., it would have been obvious to one of ordinary skill in the art at the time of the invention to form an ester linkage between the DLC film and the biocompatible material (i.e. the polyvinyl ester chains) disclosed by Pacetti et al. so that the biocompatible

material has the freedom and space to maintain their natural conformation and bioactivity.

In regard to claim 12, New et al. disclose stents made of stainless steel (a metal material) (¶ [0076]).

In regard to claims 13 – 15, Pacetti et al. disclose the medical device (base material) of their invention is a stent (Col. 1, Lines 9 - 10; Col. 18, Line 4).

3. Claims 9 - 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al. ('602), New et al. & Dang et al., as applied to claim 2 above, and further in view of Lemelson et al. (U.S. Patent No. 6,083,570).

Pacetti et al. ('602), New et al. & Dang et al. fail to disclose an intermediate layer between the medical device and the DLC layer.

Lemelson et al. disclose articles with synthetic diamond or diamond-like carbon coatings with an intermediate amorphous metal bonding layer. The residual stress in diamond and diamond-like thin film coatings applied to metal, cermet and ceramic substrates can be reduced to acceptably low levels by using an intermediate film coating of amorphous ("glassy") metal (Col. 3, Lines 54 – 65). The intermediate layer may be comprised of carbides or silicon. SiC is preferred (Col. 4, Lines 33 – 38). Such articles include dental tools and medical

prostheses or implants intended for long-term use inside the human body (Col. 4, Lines 4 - 11).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that the addition of an intermediate SiC layer between the stent and DLC thin film in the disclosure of Pacetti et al. ('602) would help to reduce the residual stress in the diamond-like carbon thin film used for medical applications. An organo-silicon intermediate layer for increased adherence between a substrate and a DLC is also disclosed by Kato et al. (U.S. Patent No. 5,763,072).

4. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti et al. ('602), New et al. & Dang et al., as applied to claim 2 above, and further in view of Pacetti (US 2005/0070936 A1).

Pacetti et al. ('602), New et al. & Dang et al. fail to disclose 2-hydroxypropyl methacrylamide as a biocompatible material in the coatings of their inventions.

Pacetti ('936) discloses a medical article, such as a stent, with a coating comprising a polymer of 2-hydroxypropyl methacrylamide as a non-fouling moiety (¶ [0008] – [0009]), which is "a compound that is capable of providing the compound with the ability to prevent or at least reduce a build-up of a denatured layer of protein on the stent surface or on the stent coating" (¶ [0028]).

Therefore, based on the teachings of Pacetti ('936), it would have been obvious to one of ordinary skill in the art at the time of the invention to prevent or

reduce a build-up of denatured protein by including 2-hydroxypropyl methacrylamide in the outer coating of the stent disclosed by Pacetti et al. ('602).

References of Note

5. Agrawal et al. (US 2003/0148401 A1) disclose a DLC coating on a substrate for a medical device, covalently bonded to a biomolecule, such as a small organic molecule.

6. Hossainey et al. (US 2003/0104028 A1) discloses DLC and polyvinyl acetate (chemical formula $-(CH_2\text{-}CHX)_n\text{-}$) layers on a substrate used as a medical device for implanting into a living organism.

7. Ding et al. (US 7,491,233), Fox et al. (US 2005/0069630 & Schottman et al. (US 2003/0203991) each disclose biocompatible coatings for implantation devices comprised of polyvinyl esters (i.e. polyvinyl acetate), which have the chemical formula $-(CH_2\text{-}CHX)_n\text{-}$.

8. Katoot (US 5,932,299) discloses grafting polymers by polymerization of monomers to impart characteristics of that monomer.

9. Dang et al. (US 6,159,531) teach using ester linkages for stable covalent bonds between biocompatible molecules and coatings applied to substrates, such as stents.

Response to Arguments

10. Applicant argues, "...the cited primary reference Steffen fails to teach the structure of a biocompatible component including polymer chains having a

structure represented by $-(CH_2\text{-}CHX)_n-$, $-(CH_2\text{-}CXY)_n-$, and $-(CHX\text{-}CHY)_n-$, as well as failing to disclose a feature in which one of the polymer chains is covalently bonded to the surface of the diamond-like carbon film. Further, the cited secondary reference(s) fail to account for the deficiencies of the primary reference" (Remarks, Pg 9).

EXAMINER'S RESPONSE: Applicant's arguments with respect to claim 2 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant argues, "Regarding the rejection of claim 8 in view of Steffen et al., Palmaz et al., as evidenced by Hamers et al., and Suto et al., Suto et al. is not prior art against the present application. As explained above, the present application has benefit of priority of March 30, 2004" (Remarks, Pg 9).

EXAMINER'S RESPONSE: Applicant's arguments with respect to Steffen et al., Palmaz et al., as evidenced by Hamers et al., and Suto et al. have been fully considered and are persuasive. The rejection over the reference of Suto et al. has been withdrawn.

12. Applicant argues, "Also regarding claim 28, this claim recites, inter alia, "...the biocompatible component is a polymer of hydrophilic 2-hydroxypropryl methacryl amide." The cited Han et al. '161 patent merely discloses poly (2-hydroxypropylmethacrylate) (HPMA), but this is not the same polymer as being instantly claimed (hydrophilic 2-hydroxypropyl methacryl amide). Thus, Hans et al. fails to disclose the claimed polymer, in addition to failing to disclose on end of

the polymer chain being covalently bonded to the surface of the diamond-like carbon film. Hans et al. '161 cannot be properly combined with the other cited references" (Remarks, Pg 10).

EXAMINER'S RESPONSE: Applicant's arguments with respect to claim 28 have been considered but are moot in view of the new ground(s) of rejection. Pacetti ('936) discloses a medical article, such as a stent, with a coating comprising a polymer of 2-hydroxypropyl methacrylamide as a non-fouling moiety (¶ [0008] – [0009]), which is "a compound that is capable of providing the compound with the ability to prevent or at least reduce a build-up of a denatured layer of protein on the stent surface or on the stent coating" (¶ [0028]).

13. Applicant argues, "Claim 29 is not in independent form…The cited Steffen reference fails to disclose these features [discussed above for claim 2]. Also, neither Palmaz '310 nor Hamers et al. teaches the claimed polymer chain being covalently bonded via an ester chain linkage to the surface of the diamond like-carbon film" (Remarks, Pg 10).

EXAMINER'S RESPONSE: Applicant's arguments with respect to claim 29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE T. GUGLIOTTA whose telephone

number is (571)270-1552. The examiner can normally be reached on M - F 8:30 a.m. - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David R. Sample/
Supervisory Patent Examiner, Art Unit 1783

/NICOLE T GUGLIOTTA/
Examiner, Art Unit 1783